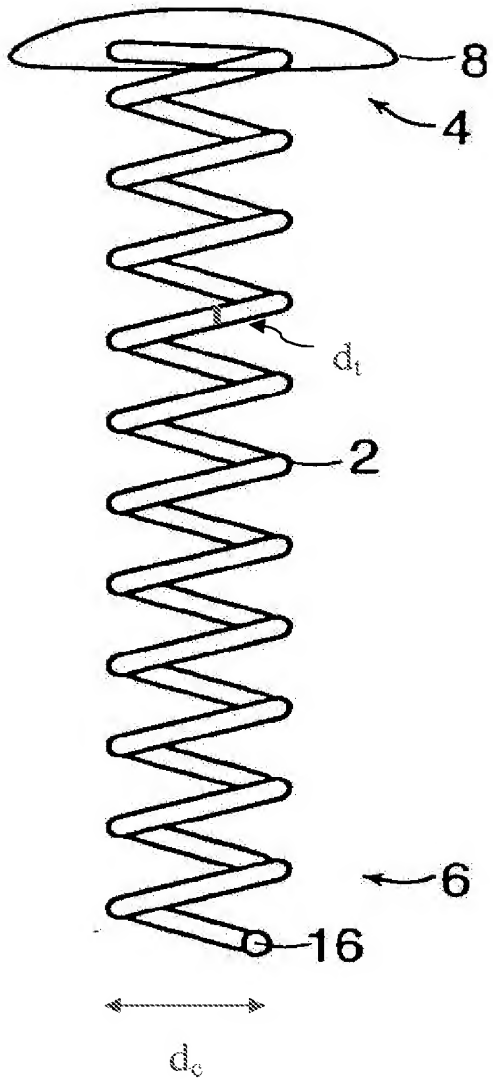
REMARKS

Claims 68-119, 122-127, 129, and 132-137 are pending in the subject application. Claims 111 and 116 are amended herein. Applicants submit that the amendments introduce no new matter, support therefore being found throughout the application and drawings as originally filed. Favorable reconsideration in light of the amendments and remarks which follow is respectfully requested.

1. Specification

The specification is objected to as not disclosing the cap element mating against the patient eye outer surface (claims 111 and 116). Without agreeing with or acquiescing to the rejection, Applicants amend claims 111 and 116 herein to recite the language "cap element is in contact with the patient eye outer surface" which is supported by the disclosure as filed as follows: in the published application (U.S. Publication 2004/0133155), at [0044] it is set out that the device is inserted into the eye with the rim or cap remaining outside of the eye until the rim or cap abuts the incision, and at [0046] it is set out that the rim or cap is fabricated of a material that does not cause irritation to the portion of the eye that it contacts. Reconsideration and withdrawal of the rejection is respectfully requested

The specification is further objected to as not disclosing the device being inserted through an incision smaller than the cross-section of the coil-shaped body member, the incision being smaller than the cross-section of the coil or zig-zag shaped body member, and the device being implantable within the patient eye through an incision smaller than the cross-section of the coil or zig-zag shaped body member. Without agreeing with or acquiescing to the rejection, Applicants amend the specification to more specifically set forth this claim language. It is submitted that the claim language is fully supported in the specification, for example, as follows: at [0037] it is set out that "the coil shape of the body member allows the device to be screwed or twisted into the eye through an incision approximately the same size as the outer diameter of the tube forming the body member 2." The device is shown below:



As shown, the body member 2 is in the form of a tube wound into a coil. As set out in the paragraph above, the device is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member. The outer diameter of the tube (which would generally be, for example, the diameter shown above as d_t) is clearly less than the cross-section of the coil-shaped body member (which would generally be, for example, as shown above as d_c).

Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. §103 Rejections

Weiner and Rosenman

Claims 68-91, 93-97, 99-109, 111-119, 122-127, 129, and 132-138 are rejected under 35 U.S.C. §103(a) over U.S. Patent No. 5,466,233 to Weiner et al. ("Weiner") and U.S. Patent No. 6,478,776 to Rosenman et al. ("Rosenman"). Applicants respectfully traverse.

Weiner describes a tack 10 for intraocular drug delivery. The tack 10 includes a post 12, a central portion having an anchoring region 14a, and a head 16 as shown below:

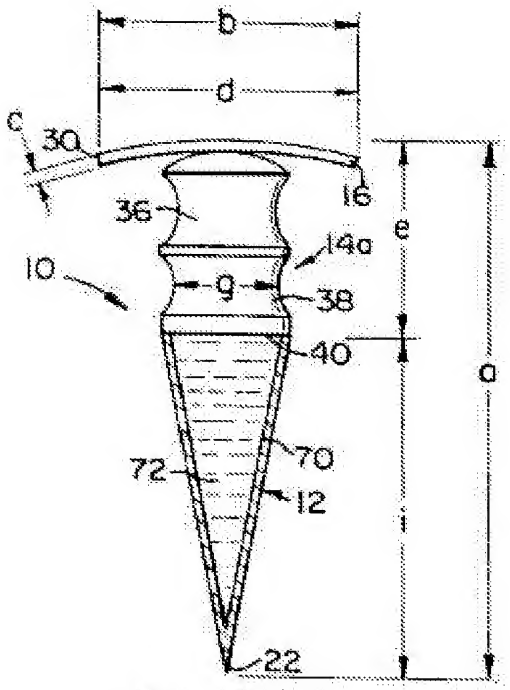
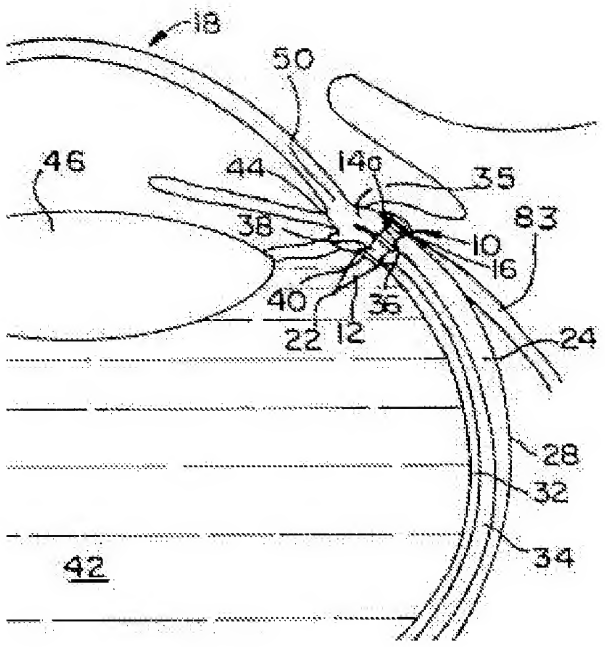


FIG. 1



As set out, the anchoring region 14a is configured so as to "secure the tack in at least one of the retina 32, the choroid 34 or the sclera 24 such that suturing is optional and movement of the tack 19 within the eye 18 once the tack 10 is in position is minimized." (col 6, lines 2-8)

As shown, Weiner's tack is provided with the anchoring region 14a secured within the retina 32, choroids 34, and/or sclera 24 and with the post 12 provided within the vitreous fluid 42. As known, the vitreous fluid is a viscous fluid that is composed of 99% water with the balance being salts, sugars, phagocytes, and a network of collagen fibers. Thus, the vitreous fluid does not, nor could it, provide any form of anchoring means for a body disposed therein. For example, as set out in Weiner at col. 2, lines 1-27, U.S. Patent No. 4,300,557 and T.J. Smith et al. provide devices that are disposed in the vitreous region of the eye and, as such, regardless of their configuration, are able to move about freely due to the viscous nature of the vitreous.

The Office, however, asserts that it would be obvious to modify Weiner's tack to provide the entire post 12 ("body member") with a coil or zig-zag shape so that the device can be properly positioned and maintained in the desired location. Applicants respectfully disagree.

Based on the teaching of Weiner, providing the post 12 in a coil or zig-zag shape would not provide additional anchoring of the device taught by Weiner. In particular, the anchoring region 14a and the head 16 are the portions of the tack 10 that provide anchoring. Due to the viscous nature of the vitreous, mechanisms positioned within the vitreous fluid are allowed to move about freely and, based on the teaching of Weiner, are not expected to provide anchoring of the device.

The Office, however, asserts that one would substitute Weiner's way of anchoring the device with Rosenman's way of anchoring the device. Applicants respectfully disagree. Weiner describes a method and configuration for anchoring a device within a location that is mostly viscous fluid. Rosenman, on the other hand, describes a method and configuration for anchoring a device within solid tissue. Clearly one could not anchor a device in a viscous fluid (in which any device, regardless of configuration, would be allowed to move about freely) the same way that one could anchor the device in solid tissue.

In particular, Rosenman describes a helical device that is implanted within the cardiac tissue below the surface of the tissue. Because the helical device is implanted within solid tissue, the helical shape provides a method for anchoring the device in place in the solid tissue. Weiner, on the other hand, describes a tack that is implanted in the eye with a drug delivery portion (post 12) disposed in the vitreous fluid. The portion of the device in the vitreous fluid, no matter what its configuration, does not provide a mechanism for maintaining or anchoring the device in place in the vitreous fluid. To prevent the tack from moving freely about within the viscous vitreous fluid, Weiner requires that the tack include a head 16 which remains exterior the eye on the solid outer surface of the eye to prevent the entire tack from passing into the vitreous fluid of the eye, and which can be further sutured to the eye. Weiner also provides an anchoring region 14a that is configured for secure positioning of the device in the outer layers of solid tissue of the eye (sclera, choroids, and/or retina). Anchoring regions are not further provided in the post 12 of the tack, nor would any such regions be expected to successfully or beneficially provide additional anchoring means within the vitreous fluid.

It is submitted that one method for anchoring a device within a patient's body cannot be simply substituted for another method for anchoring a device within another part of a patient's body without taking into account the location in the body and the characteristics and properties of the location. Clearly, anchoring a device within a viscous fluid could not be accomplished the same way as one would go about anchoring a device within a solid material or within a lumen (e.g. a blood vessel), nor would one expect that it could be successfully accomplished the same way. In this case, providing the post 12 of Weiner in a helical shape (based on Rosenman's disclosure) would not be expected by one of skill in the art to provide any additional anchoring advantage or beneficial result to Weiner because the post is located within a viscous fluid.

In view of the above, it is respectfully submitted that there is no teaching or suggestion to modify Weiner in view of Rosenman as proposed by the Office or that such a modification would provide any likelihood of success.

Accordingly, claims 68, 79, 83, 93, 99, 111, 116, and 129, and all claims dependent therefrom, are patentable over Weiner and Rosenman. Reconsideration and withdrawal of the rejections is respectfully requested.

Weiner and Rosenman and Johnson

Claims 92, 98, and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner, Rosenman, and U.S. Patent No. 5,972,027 to Johnson ("Johnson"). Applicants respectfully traverse.

As set forth above, Weiner and Johnson fail to teach or suggest Applicants' devices or methods as recited in independent claims 83, 93, and 99. Johnson is cited for allegedly describing shape memory materials. However, Johnson does not remedy the above-noted deficiencies in Weiner and Rosenman.

Accordingly, claims 92, 98, and 110 (which depend from claims 83, 93, and 99) are patentable over Weiner, Rosenman, and Johnson. Reconsideration and withdrawal of the rejections is respectfully requested.

CONCLUSION

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

If for any reason the fee paid is inadequate or credit is owed for any excess fee paid, the Office is hereby authorized and requested to charge Deposit Account No. **04-1105**.

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Respectfully submitted,
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